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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/682,706	10/09/2001	Sheau Yu Hsu	STAN210	1555

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EXAMINER

LI, RUIXIANG

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/682,706

Applicant(s)

HSU ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5 is/are pending in the application.
- 4a) Of the above claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicants' election with traverse of Group I (claims 1-3) and SEQ ID NO: 3 in Paper No. 9 filed on 02/24/2003 is acknowledged. The traverse is on the ground (i) that SEQ ID NO: 3 is mature form of the polypeptide of SEQ ID NO: 2 and the sequences should be examined together; (ii) SEQ ID NO: 3 and SEQ ID NO: 6 should be examined together because they show considerable sequence similarity; and (iii) claim 5 of Group III requires the use of the peptide of claim 3 of Group I and should be rejoined.

The arguments (ii) and (iii) have been fully considered but is not deemed to be persuasive because the amino acid sequence restriction requirement set forth in previous office action in Paper No. 7 (12/13/20020) is not a species election requirement, rather it sets forth further invention groups. This is because each of the sequences represents a structurally and functionally distinct entity that is capable of supporting a separate patent. The search and consideration of all of the sequences constitutes an undue search burden on the office, given the ever-increasing size of the database. The Examiner notes that when claims 1-3 are allowable, applicants request that Group III be rejoined with group I will be considered.

In view of applicants argument (i) that SEQ ID NO: 3 is the mature form of SEQ ID NO: 2, the Examiner will search and examine SEQ ID NO: 3 together with SEQ ID NO: 2.

The requirement is still deemed proper and is therefore made FINAL.

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2. Applicants' amendment in Paper No. 9 filed on 02/24/2003 has been entered in full. Claims 4 and 6-22 have been canceled. Claims 1-3 and 5 are pending. Claims 1-3 are under consideration.

Priority

3. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §119(e) to provisional applications 244,128 (filed on 10/26/2000) and 60/276,615 (filed on 03/15/2001).

Drawings

4. The drawings filed on 10/09/2001 are accepted by the Examiner.

Claim Rejections—35 USC § 112, 1st paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising an isolated polypeptide of SEQ ID NO: 2 or its mature form of SEQ ID NO: 3, does not reasonably provide enablement for a composition comprising an isolated polypeptide comprising at least 18 or 30 contiguous amino acids of SEQ ID NO: 2 or SEQ ID NO: 3.
3. The specification does not enable any person skilled in the art to which it pertains,

or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claims 1-3 are drawn to a composition comprising a genus of polypeptides, which comprises at least 18 or 30 contiguous amino acids of SEQ ID NO: 2 or SEQ ID NO: 3. There is no functional limitation in the claims. Thus, the scope of the claims is broad. Applicants have taught the mature form (SEQ ID NO: 3) of full-length stresscopin 1 polypeptide (SEQ ID NO: 2) and truncated peptides with deletion of 1 to 5 amino acids at the terminus stimulated cAMP production by recombinant CRHR2 receptor (Fig. 3). Applicants have also taught that treatment with the polypeptide of SEQ ID NO: 3 decreased food intake in fasting mice and suppressed gastric emptying activity, whereas a truncated peptide with a deletion of first 10 amino acids at the N-terminus has no effect on food intake in mice (Fig. 4). While the specification suggests that the polypeptide of SEQ ID NO: 2 or SEQ ID NO: 3 is a ligand of CRHR2 receptor, the specific binding domains is not disclosed. Thus, claims 1-3 encompass an unreasonable number of inoperative polypeptides, which one skilled artisan would not know how to make and use. The prior art does not provide any

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information on how to make and use the claimed composition comprising the broad genus of polypeptides, which comprises at least 18 or 30 contiguous amino acids of SEQ ID NO: 2 or 3.

Other than SEQ ID NO: 2 and 3 and the truncated peptides with deletion of 1 to 5 amino acids at the terminus of SEQ ID NO: 3, there are no additional working examples of using polypeptides comprising the fragments of SEQ ID NO: 2 or 3. The skilled artisan would not know how to use the unidentical peptides on the basis of teachings in the prior art or specification unless they possessed the activity disclosed in the instant specification. Since there is no functional limitations and the binding domain of the polypeptide of SEQ ID NO: 2 or 3 is not disclosed, the specification does not provide guidance for using polypeptides comprising fragments of SEQ ID NO: 2 or 3.

Therefore, it would require undue experimentation for one skilled in the art to make and use the composition comprising an isolated polypeptide comprising at least 18 or 30 contiguous amino acids of SEQ ID NO: 2 or SEQ ID NO: 3.

7. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a composition comprising a polypeptide, which comprises at least 18 or 30 contiguous amino acids of SEQ ID NO: 2 or SEQ ID NO: 3. The claims do not require that the polypeptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing

feature. Thus, the claims are drawn to a genus of polypeptides that is defined only by partial sequence identity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a partial structure in the form of a recitation of comprising at least 18 or 30 contiguous amino acids of SEQ ID NO: 2 or SEQ ID NO: 3. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of

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the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only compositions comprising the full-length stresscopin 1 polypeptide (SEQ ID NO: 3) or its mature form set forth in SEQ ID NO: 3, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections—35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351() shall have the effects for the purpose of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English.

9. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Vale et al. (WO 02/12307-A1, published on February 14, 2002; priority date, August 4, 2000).

Vale et al. teach an amino acid sequence, which is 100% identical to SEQ ID NO: 2 (See attached sequence alignment). This amino acid sequence is 95.5%

identical to SEQ ID NO: 3, with 29 contiguous amino acid of SEQ ID NO: 3 (See attached sequence alignment). Vale et al. also teach a composition comprising the polypeptides and a pharmaceutically acceptable carrier (see, e.g., claim 13). Thus, the reference of Vale meets the limitations of claims 1-3.

Claim Objections—Minor Informalities

10. Claims 1-3 are objected to because they recite unelected subject matter, amino acid sequences.

Claim 2 is also objected because of a typographic error; "A composition" should be replaced by "The composition".

Appropriate correction is required.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on 2/25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
April 3, 2003


YVONNE EYLER, PH.D.
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